Clinical Review APPENDIX SUBSECTION 6.1 MedWatch Forms for Cases of Special Interest

CRESTOR (ZD4522, rosuvastatin calcium) Tablets FDA Advisory Committee Meeting Briefing Document NDA 21-366 for the use of CRESTOR June 11, 2003

6.1 MedWatch Forms for Cases of Special Interest:

- 1. MedWatch Report of a case of 68 year old patient with Jaundice and Transaminase elevation on 10mg of Rosuvastatin <u>D3560L0001/0310/01237</u>
- 2. MedWatch Report of a case of 73 year old patient with Jaundice and Transaminase elevation on 10mg of Rosuvastatin D3560L0001/2265/09060
- 3. MedWatch Report of a case of Rhabdomyolysis on 10mg of Rosuvastatin 2003SE02255
- 4. MedWatch Report of a case of 46 year old patient with Renal Failure on 80mg of Rosuvastatin 0065/0044/0014
- 5. MedWatch Report of a case of 70 year old patient with Renal Failure on 80mg of Rosuvastatin 0065/0026/0049
- 6. MedWatch Report of a case of 69 year old patient with Interstitial Nephritis on 80mg of Rosuvastatin <u>0034/0316/0025</u>